IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

The Regents of the University of California,

Plaintiff/Counterclaim Defendant,

v.

Micro Therapeutics Inc., et al.,

Defendants/Counterclaimants/Third Party Plaintiffs

v.

Boston Scientific Corp., et al.,

Third Party Defendants.
_____/

NO. C 03-05669 JW

ORDER DENYING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF INVALIDITY OF THE PATENTS-IN-SUIT FOR FAILURE TO COMPLY WITH 35 U.S.C. § 112, ¶¶ 1, 2 AS TO THE BEST MODE REQUIREMENT AND INDEFINITENESS

I. INTRODUCTION

Plaintiff The Regents of the University of California ("The Regents") brings this action against Defendants Micro Therapeutics Inc. ("MTI") and its wholly owned subsidiary Dendron GmbH (collectively, "Defendants") for infringement of twelve of The Regents' patents which relate to devices for occluding vascular cavities for the treatment of brain aneurysms. Presently before the Court is Defendants' Motion for Summary Judgment of Invalidity of the Patents-In-Suit for Failure to Comply with 35 U.S.C. § 112, ¶¶ 1 and 2. The Court conducted a hearing on June 5, 2007. Based on the papers submitted to date and the oral arguments of counsel, the Court DENIES

Defendants' Motion for Summary Judgment on the issues of the best mode requirement and indefiniteness.[1]

II. BACKGROUND

The Regents own the twelve patents-in-suit, all of which relate to endovascularly inserted detachable coils for the treatment of brain aneurysms. At present, The Regents assert seven of those patents against Defendants: United States Patent Nos. 5,122,136 ("the '136 patent"), 5,855,578 ("the '578 patent"), 6,066,133 ("the '133 patent"), 5,976,126 ("the '126 patent"), 5,947,962 ("the '962 patent"), 5,947,963 ("the '963 patent"), and 5,925,037 ("the '037 patent"). In addition to these seven patents, Defendants' counterclaims include five additional patents:[2] U.S. Patent Nos. 5,354,295 ("the '295 patent"), 5,540,680 ("the '680 patent"), 5,895,385 ("the '385 patent"), 6,010,498 ("the '498 patent"), and 6,083,220 ("the '220 patent").

All twelve patents-in-suit are part of a family of patents arising from application United States Serial No. ("USSN") 07/492,717 ("the '717 application"), filed on March 13, 1990.[3] The '717 application was issued as the '136 Patent. Id. Following the '717 application, continuation, continuation-in-part and divisional applications were filed to give rise to the remaining patents-in-suit. Id.

//

[1] The Court will issue a separate order ruling on Defendants' motion for summary judgment of invalidity based on the written description requirement.

[2] The Regents originally asserted all twelve patents-in-suit against Defendants. They subsequently dropped five of the patents from their claims: U.S. Patent Nos. 5,354,295 ("the '295 patent"), 5,540,680 ("the '680 patent"), 5,895,385 ("the '385 patent"), 6,010,498 ("the '498 patent"), and 6,083,220 ("the '220 patent"). Those five patents remain in suit as part of Defendants' counterclaims. (See, e.g. Supplemental Joint Case Management Statement, Docket Item No. 332.)

[3] (Declaration of C.J. Alice Chuang in Support of Plaintiff's Consolidated Opposition to Defendants' Motions for Partial Summary Judgment of Invalidity Ex. 2, hereafter, "Chuang Decl.," Docket Item No. 549.)

Presently before the Court is Defendants' Motion for Summary Judgment of Invalidity of the Patents in Suit for Failure to Comply with 35 U.S.C. § 112, ¶¶ 1 and 2. The Court addresses the best mode requirement and indefiniteness issues in this Order.

III. STANDARDS

Summary judgment is proper "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The purpose of summary judgment "is to isolate and dispose of factually unsupported claims or defenses." Celotex v. Catrett, 477 U.S. 317, 323-24 (1986). The moving party "always bears the initial responsibility of informing the district court of the basis for its motion, and identifying the evidence which it believes demonstrates the absence of a genuine issue of material fact." Id. at 323. The non-moving party must then identify specific facts "that might affect the outcome of the suit under the governing law," thus establishing that there is a genuine issue for trial. Fed. R. Civ. P. 56(e).

The court draws all reasonable inferences in favor of the non-moving party, including questions of credibility and of the weight that particular evidence is accorded. See, e.g. Masson v. New Yorker Magazine, Inc., 501 U.S. 496, 520 (1992). The court determines whether the non-moving party's "specific facts," coupled with disputed background or contextual facts, are such that a reasonable jury might return a verdict for the non-moving party. T.W. Elec. Serv., 809 F.2d at 631. In such a case, summary judgment is inappropriate. Anderson, 477 U.S. at 248. However, where a rational trier of fact could not find for the non-moving party based on the record as a whole, there is no "genuine issue for trial." Matsushita, 475 U.S. at 587.

IV. DISCUSSION

A. Best Mode Requirement

Defendants move for summary judgment on the ground that all asserted claims of the patents-in-suit are invalid for failure to satisfy the best mode requirement. (Defendants' Motion for

Summary Judgment for Invalidity of the Patents in Suit for Failure to Comply with 35 U.S.C. § 112, ¶¶ 1 and 2 at 2-17, hereafter, "Motion," filed under seal.)

Title 35 U.S.C. § 112 provides that a patent specification must "set forth the best mode contemplated by the inventor of carrying out the invention." 35 U.S.C. § 112 ¶ 1. To determine whether the best mode requirement is satisfied, the court considers whether (1) the inventor subjectively considered a particular mode of practicing the invention to be superior to all other embodiments at the time the application was filed and (2) if so, whether he or she provided a sufficient disclosure to allow others to practice that best mode. Go Med. Indus. Pty., Ltd. v. Inmed Corp., 471 F.3d 1264, 1271 (Fed. Cir. 2006).

Compliance with the best mode requirement is a question of fact. Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1312 (Fed. Cir. 2002) (internal citations omitted). The Federal Circuit has invalidated patents for failure to satisfy the best mode requirement in two circumstances: (1) where the patent does not adequately disclose a preferred embodiment of the invention or (2) where the patentee failed to disclose aspects of making or using the claimed invention and the undisclosed matter materially affected the properties of the claimed invention. Id. at 1319. A best mode violation may occur where the disclosure of the best mode is so objectively inadequate as to conceal the best mode from the public. United States Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1215 (Fed. Cir. 1996).

The best mode inquiry focuses on the inventor's state of mind at the time the patent application was filed. Gargoyles, Inc. v. United States, 113 F.3d 1572, 1582 (Fed. Cir. 1997) The duty to disclose the best mode extends only to details of which the inventor is personally aware. Id. Knowledge of the commercial embodiment—if different from what was in the inventor's mind at the time the patent application was filed—is not imputed to the inventor. Id. This is because the sole purpose of a best mode violation is "to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived." Id.

Defendants contend that the '717 application failed to disclose the best mode requirement in four primary areas. The Court discusses each of these in turn.

1. Proximal "Filler" Coil

Defendants first contend that the '717 application failed to disclose the use of a proximal "filler" coil necessary for joining the stainless steel detachment coil to the core wire. (Motion at 3.) The Regents contend that the use of the proximal coil was a mere "manufacturing detail" or "soldering technique" that did not require disclosure in the '717 application. (Opposition at 19-20.)

Defendants have presented the following evidence in support of their motion:

Before March 13, 1990, Target Therapeutics, Inc.[4] ("Target") was making Guglielmi detachable coils ("GDCs") by preparing individual components or assemblies, and assembling them into the final product. Target's master protocol was a "Lot History Record" ("LHR R-213"), which provided the overall steps for making the GDC. Target also had sub-protocols, "Manufacturing Process Instructions" ("MPIs"), which provided a detailed description for each step in the LHR.

On January 24, 1990[5], co-inventor Ivan Sepetka ("Sepetka") and Target engineer Phong Pham ("Pham") developed MPI-R214, which described how to prepare the main GDC assembly. Sepetka approved this MPI on the same day.[6]

However, Sepetka and Pham developed the first version of LHR R-213 and put it in effect on February 6, 1990. (Bina Decl., Exs 15-25, 32 and 33.) Sepetka, as Research and Development

---

[4] Boston Scientific Corporation and Target Therapeutics, Inc., a wholly-owned subsidiary of Boston Scientific, are Third Party Defendants in this case. Target is the owner by assignment of U.S. Patent No. 6,238,415, entitled "Implant Delivery Assembly with Expandable Coupling/Decoupling Mechanism," and is the exclusive licensee of U.S. Patent No. 5,895,385, entitled "Endovascular Electrolytically Detachable Wire and Tip for the Formation of Thrombus in Arteries, Veins, Aneurysms, Vascular Malformations and Arteriovenous Fistulas" and U.S. Patent No. 6,010,498 with the same title as the '385 Patent.

[5] Each of the underlined dates occurred before the inventors' March 13, 1990 filing date of the '717 application.

[6] (Declaration of Gabrielle E. Bina in Support of Defendants' Motion for Summary Judgment of Invalidity of the Patents in Suit for Failure to Comply with 35 U.S.C. § 112, ¶¶ 1 and 2, **Ex. 19**; **Ex. 18** at 117:13-119:21, hereafter, "Bina Decl.," submitted under seal.)

Project Manager, approved LHR R-213 on March 9, 1990. (Bina Decl., **Ex. 18** (Pham Dep.) at 97:13-98:4, 103:5-13; **Ex. 15** at 39.) On March 13, 1990, the '717 application was filed. The section entitled "Detailed Description of the Preferred Embodiments" provided:

> The stainless steel guidewire 10 [is] comprised of that portion disposed within the microcatheter body, tapered section 12 to second bonding location 22 . . . **A stainless steel coil is soldered to the proximate end of threadlike portion 18 of guidewire 10 at first bonding location 20**.[7]

(Bina Decl., Ex. 13 at 10.) The instructions direct the reader to solder the stainless steel coil directly to the core wire. Moreover, the '211 CIP application recited the '717 application's teaching—soldering the stainless steel coil directly to the core wire—verbatim. (Bina Decl., Ex. 2 ('295 patent) at col 7:50-54.)

In contrast, LHR R-213 directs the reader to wind, stretch, and cut a proximal coil. (Bina Decl., Ex. 16.) After the proximal coil has been cut, it is inserted onto the core wire; subsequently, the stainless steel coil is inserted onto the proximal coil and core wire. Id. The procedure is described in more detail in MPI-R214. (Bina Decl., **Ex. 19**.) Pham explained the reason for using the proximate coil as follows:

> Q: And is it usually screwed on, that the top [stainless steel] coil is screwed onto the filler [proximate] coil?
>
> A: Not necessarily. This is just support for soldering. It is the technique for soldering. So you just have to attach the longer coil, the outer coil, to the core wire.
>
> Q: Okay. And is that because the core wire is at a point where it's tapering, and so the filler coil helps increase the diameter so that the outer coil can cleanly attach?
>
> A: Yes. You got it.
>
> Q: Okay. Why wouldn't you just solder the outer coil onto the core wire?
>
> A: Very hard to solder just only the coil. Because the gap between the core wire – you notice at the distal section, the core wire will route down to 2,000ths (sic) of an inch. And the – in the ID of the coil, the big coil, is very large. It's seven or – so we need something to fill the coil, just support for the coil so the operator can solder the outer coil through the inner coil and the core wire. It's a technique.

(Bina Decl., **Ex. 18** (Pham Dep.) at 39:2-23.)

---

[7] The bolded language appears verbatim in the '136 patent. (Bina Decl., Ex. 1.)

The Regents have submitted the following evidence in opposition to Defendants' motion:

Neither of the inventors had a proximal filler coil in mind as part of the best mode of practicing their invention. Specifically, Guglielmi considered this to be a "manufacturing detail" in which he was not involved. (Guglielmi Decl. ¶¶ 10-11.) Sepetka did not consider the soldering technique to be a particular mode of practicing the invention, and had not determined what the best method would be.[8] (Sepetka Decl. ¶¶ 8-9.)

The evidence presently before the Court suggests that Guglielmi was not closely involved with issues relating to GDC assembly, such as the use of the proximal "filler" coil. The current evidence also suggests that Sepetka had reviewed protocols, prior to March 13, 1990, describing the use of the proximal coil. As such, the relevant inquiries are (1) whether Sepetka subjectively considered the preferred embodiment of the GDC to include the proximal/filler coil or (2) whether the use of the proximal/filler coil materially affects the properties of the claimed invention (or conversely, whether use of the proximal coil was a manufacturing detail not material to the best mode analysis). Both inquiries involve triable questions of material fact and thus, must be resolved by the factfinder at trial.

2. Zapping

Defendants contend that the '717 application failed to disclose the Target trade secret of "zapping" to produce the distal tips. (Motion at 3.) The Regents contend that: (1) Defendants have failed to link the "zapping" technique to any specific patent claim; and (2) Defendants have failed to present evidence from either co-inventor saying that they thought "zapping" was the best technique for smoothing or rounding coil tips. (Opposition at 20-21.)

[8] Sepetka stated, "We used a medical grade gold solder to improve the strength of the bond between the wire and coils. We could have used other bonding techniques instead, such as medical grade glue. We also could wind the filler coil from a different metal such as iridium rather than platinum." (Sepetka Decl. ¶ 8.)

Defendants have presented the following evidence in support of their motion:

Each of the patents-in-suit teach that a platinum soldered tip is attached to the end of the platinum embolic coil in order "to avoid puncturing the aneurysm or tearing tissue." (See, e.g. Bina Decl., Ex. 1 ('136 patent) at col. 6:35-38; Ex. 2 ('295 patent) at col. 7:67-8:2.) In contrast, LHR R-213 and MPI-R214 direct the reader to "[f]use and smooth the tip of the Microcoil by the 'Zapper.'" (Bina Decl., **Exs. 16, 19**.) In 1989 correspondence with the Food and Drug Administration, Target described the "zapping" process:

> The [MicroArc] unit[9] is used to generate a quick and clean source of heat. By directing arc at the bare, cut tips/ends of coils, melting occurs. The heat produced is thus regionalized to affect only the extreme tips of the coil. Smooth, rounded tips/ends are achieved using this method which results in atraumatic tips/ends on the coil which is an important attribute for ease of delivery through a Tracker-18 catheter and for safety in placement of coil at final target site.

(Bina Decl., **Ex. 24**.) As for why "zapping" was preferable to soldering, Target stated:

> Target Therapeutics Coils have a fused tip rather than using solder. The tip fusing process does not require the introduction of any other materials such as solder or other metal. This results in a more stable device with less likelihood of degradation than that which may occur in bimetal or other multimetal implants. The current literature on metallic implants suggests that monometallic implants are less bioreactive and more stable than multi-metal implants.

Id.

The Regents have presented the following evidence in opposition to Defendants' motion:

Sepetka considered "zapping" to be one of multiple ways to make a coil atraumatic. (Carbajal Decl. **Ex. 29** at 42:8-43:2 (9/17/04 Sepetka Dep.); **Ex. 27** at 130:9-18; 132:1-16; 139:2-17 (2/13/07 Pham Dep.) (describing other methods of making a coil atraumatic)). Sepetka did not consider "zapping" to be a superior or preferred method of making the GDC devices at either the

---

[9] Target described the MicroArc unit as "consist[ing] of a high energy, high frequency sold state electronic flyback circuit (high voltage power supply) capable of producing an electrical arc with enough power to fuse/melt certain metals which exhibit melting points lower than 1000 deg. F. A probe is connected to the positive output of the flyback circuit to allow positioning of arc at desired "Arc Point". (Bina Decl., Ex. 24.)

time of the original or the continuation application.[10] (Sepetka Decl. ¶¶ 10-11.) Guglielmi similarly stated:

> While I was interested in ensuring that the tip did not perforate the aneurysm, and I thought a rounded tip was a good approach for that, I did not have a preference at the time for the process by which the tip was rounded. Nor did I have such a preference at the time that we filed the continuation-in-part application, on February 24, 1992. In general, I was not involved in such engineering details for the commercial products that Target developed based on our invention.

(Guglielmi Decl. ¶ 11.)

The evidence suggests that "zapping" coil tips was a GDC assembly issue with which Guglielmi was not involved. Moreover, the evidence suggests that Sepetka had reviewed protocols, prior to March 13, 1990, that described the use of a "Zapper" to fuse and smooth coil tips. The relevant inquiries, then, are (1) whether Sepetka subjectively considered the preferred embodiment of the GDC to include coils with "zapped" distal tips or (2) whether the use of "zapped" rather than soldered distal tips materially affects the properties of the claimed invention (or conversely, whether "zapping" the distal tips was a manufacturing detail not material to the best mode disclosure). Since there exist triable issues of material fact as to both inquiries, both must be resolved by the factfinder at trial.

3. "Deposited Multiple Coils Into Systemically Heparinized Patients"

Defendants contend that the '717 application and the '136 patent teach the following process for occlusion: "(1) place a single tip into the aneurysm, (2) apply current to form thrombus until the aneurysm is completely occluded, and (3) apply more current to the tip, leaving it 'embedded within the thrombus formed within the aneurysm, leaving it completely occluded . . ." (Motion at 13.) Defendants contend that Guglielmi had abandoned this method prior to the filing of the '717 application, in favor of one in which he "deposited ***multiple coils*** into systemically heparinized

---

[10] Sepetka stated, "While I wanted to design a device that would not perforate the aneurysm, I did not have a preference at the time I filed the original patent application for the process by which the tip was rounded. I also did not have a personal preference for the best method for manufacturing the rounded tips for the commercial GDC devices when we filed the continuation application on February 24, 1992." (Sepetka Decl. ¶ 11.)

patients, followed by administration of protamine sulfate to achieve a delayed, mechanical occlusion." (Motion at 13, emphasis in original.)

i. Use of Heparin and Protamine Sulfate

Defendants have presented the following evidence in support of their motion:

In 1991, Guglielmi and co-authors published an article in the Journal of Neurosurgery entitled, "Electrothrombosis of saccular aneurysms via endovascular approach. Part 2: Preliminary clinical experience," summarizing fifteen endovascular electrothrombosis procedures on high-risk aneurysms they performed between March and November 1990. (Bina Decl., Ex. 26.) The article describes the potential to use multiple coils: "It is possible to introduce, deliver, and detach more than one coil in the aneurysm, depending on the size of the lesion." Id. The article also describes the doctors' use of heparin and protamine sulfate in each procedure: "All procedures are performed with the patient awake and under systemic heparinization . . . At the end of the embolization procedure . . . . [t]he heparinization is reversed by administration of protamine sulfate." Id. Lastly, the article described the time progression of intra-aneurysmal thrombosis:

> Intra-aneurysmal thrombosis progresses with time. It is believed that this is due to two factors: 1) in the hours that follow embolization more blood components are trapped within the network of coils; and 2) during the procedure systemic heparinization impedes intra-aneurysmal clot formation and, as soon as heparin is reversed, clot formation within the coils is enhanced.

Id. (emphasis added).[11]

The Regents have presented the following evidence in opposition to Defendants' motion:

Heparin is a common anticoagulant mechanism.[12] At the time of the invention, heparin was commonly used in neuroradiological interventional procedures to prevent blood clots from forming

---

[11] Guglielmi described the first human GDC procedure he performed on March 9, 1990, in his 1992 article in *Neurosurgery* entitled, "Carotid-Cavernous Fistula Caused by a Ruptured Intracavernous Aneurysm: Endovascular Treatment by Electrothrombosis with Detachable Coils." (Bina Decl., Ex. 27.)

[12] (Declaration of Dr. Gary Nesbit in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment of Invalidity for Failure to Comply with 35 U.S.C. § 112 ¶¶ 1 and 2, ¶ 55, hereafter, "Nesbit Decl.," Docket Item No. 646.)

as the result of catheterization, diagnostic tools, or treatment. Id. It was discussed in several of the prior art articles relied on by experts in this case. (Nesbit Decl. ¶ 56, Exs. B, C.) Guglielmi did not consider heparin to be a critical part of the claimed invention, but rather, "a routine detail of medical practice in interventional radiology." (Guglielmi Decl. ¶ 12.) Sepetka had no input into the drugs used in medical procedures involving the GDC. (Sepetka Decl. ¶¶ 14, 17.)

Protamine sulfate is a drug that reverses the anticoagulant effects of heparin by binding to it. (Nesbit Decl. ¶ 57.) At the time of the invention, protamine sulfate was commonly used to reverse doses of heparin administered in surgical procedures, including neuroradiological procedures. Id. Guglielmi considered protamine sulfate to be an option for use in GDC procedures, but did not have an absolute preference for it and did not use it on a consistent basis at the time that the '717 application was filed. (Guglielmi Decl. ¶¶ 12-14.)

The evidence suggests that Sepetka was uninvolved with the medical decisions to use heparin and protamine sulfate in clinical procedures involving the GDC. The evidence also suggests that Guglielmi was quite familiar with the use of heparin and protamine sulfate in endovascular electrothrombosis procedures. The relevant inquiries, then, are (1) whether Guglielmi subjectively considered the preferred method for aneurysm occlusion via the GDC to include the use of heparin and protamine sulfate and (2) whether the use of heparin and protamine sulfate materially affects the disclosed occlusion process (or, conversely, whether use of these drugs constitutes a routine detail of medical practice.) Since there exist triable issues of material fact as to both inquiries, both must be resolved by the factfinder at trial.

ii. Multiple Coils

Defendants have submitted the following evidence in support of their motion:

Guglielmi provided the following explanation of the use of multiple coils in a GDC procedure at deposition:

> Q. Now, if the first coil had caused an occlusion, would it have been proper to insert a second coil?
> . . .

> A. The occlusion of a fistula is not an immediate event with coils. It's an event that takes place in the hours that follow the procedure.
>
> Q. Is it then possible that the first coil alone would have caused the occlusion had you waited a little?
> . . .
>
> A. No. You cannot wait and see because the patient is full of heparin.
>
> Q. And what is the consequence to the patient of - -
>
> A. The blood, the blood cannot clot.
>
> Q. So you need to make the judgement [sic] of how many coils you insert at the time of the of the (sic) surgery?
>
> A. Yes, with your experience, your knowledge, your judgement [sic].
> . . .
> Q. And after [the first coil] detaches, did you consider then whether the aneurysm had been filled enough by the first coil before inserting the second coil?
> . . .
> A. You look at the monitor, you do a control angiogram and you decide, based on your experience, if one coil is enough or if you have to add another coil.

(Bina Decl., Ex. 28 (Guglielmi Dep.) at 424:21-428:2.)

Additionally, Guglielmi's 1991 Journal of Neurosurgery paper summarizes several procedures in which multiple coils were detached in human patients; two of those procedures occurred before the March 13, 1990 filing date of the '717 application.[13] The paper provides explicitly, "It is possible to introduce, deliver, and detach more than one coil in the aneurysm, depending on the size of the lesions." (Bina Decl., Ex. 26.)

Lastly, in discovery, The Regents admitted as follows:

> Request for Admission No. 26: Admit that U.S. patent application Serial No. 492,717, filed March 13, 1990, does not disclose systemic heparinization of patients during a procedure in which multiple coils are detached electrolytically to achieve mechanical occlusions of aneurysms.
>
> (Objections.)
>
> Admitted.

(Bina Decl., Ex. 30.)

---

[13] The Regents confirmed the use of multiple coils in procedures occurring before March 13, 1990 in their response to Defendants' Request for Admission No. 27. (Bina Decl., Ex. 30.)

The Regents have presented the following evidence in opposition to Defendants' motion:

At the time of the '717 application, Guglielmi had not concluded that more than one coil was the best practice for all procedures. To the contrary, he states: "I believed, and subsequently taught doctors who were trained for the clinical trials of the GDC devices in 1990 and 1991, that some aneurysms would require only a single coil, and that others would require multiple coils."[14] (Guglielmi Decl. ¶ 8.) During initial testing, physicians recommended patients to the inventors for the study who presented "very tough cases, for example, where the aneurysm was difficult to reach or involved giant aneurysms." (Sepetka Decl. ¶ 15.) Both of the patients who were treated prior to March 13, 1990, involved unique or rare occurrences. (Guglielmi Decl. ¶¶ 6-7.) Lastly, Sepetka states in his declaration:

> I was not present in the operating room during the surgical procedure for the first two patients who were treated using GDC prototype devices. I am not a medical doctor and thus when we filed the original patent application, I did not know and did not have a preference on whether the best method for treating patients was to use a single coil of a particular diameter and length or to use multiple coils, or whether the best technique would vary from patient to patient.

(Sepetka Decl. ¶ 14.)

The evidence again suggests that Sepetka was uninvolved with the medical decisionmaking underlying the use of multiple coils in a GDC procedure. The undisputed evidence is that Guglielmi had performed GDC procedures involving multiple coils prior to the filing of the '717 application. The relevant inquiries are whether (1) as of the filing of the '717 application, Guglielmi subjectively preferred the use of multiple coils in GDC procedures (or conversely, whether Guglielmi subjectively believed that single coils would be preferable in some cases, and multiple coils in others) and (2) whether the use of multiple coils was known to affect the occlusion process

---

[14] Nesbit's declaration corroborates this: "It has been my experience that the number of coils one uses during a medical procedure using the GDC devices varies depending on the nature and extent of the condition being treated. A treating physician may elect to use just one coil, multiple coils, or one or more coils together with other adjunct treatments such as balloon embolization." (Nesbit Decl. ¶ 52.)

materially, such that it became part of the best mode of practicing the invention. There exist triable issues of material fact as to both inquiries, and both must be resolved by the factfinder at trial.

4. Electrolytic Detachment of the Distal Tips

Defendants contend that the '717 application failed to disclose the preferred embodiment for electrolytically detaching the distal tips. (Motion at 16.)

Defendants have submitted the following evidence in support of their motion:

Every patent in suit states that "the invention may include conventional electronics connected to the proximal end of the [guidewire/wire] for determining the exact instant of detachment of the distal tip from the [guidewire/wire]." (See, e.g. Bina Decl., Ex. 1 at col. 8:64-68; Ex. 2 at col. 13:4-7.) As of the filing of the '717 application, Target had developed a preferred embodiment for electrolytic detachment that was not disclosed in the application. (Bina Decl., **Ex. 16**.) Specifically, Target had a DC "Power Supply Part." Id.

The Regents have submitted the following evidence in opposition to Defendants' motion:

For at least the first ten procedures that Dr. Guglielmi performed on humans (including the two performed before the '717 application was filed), he used a generator that he made himself.[15] The Target detachment box cited by Defendants was not available during the initial procedures that Dr. Guglielmi performed. (Carbajal Decl., **Ex. 24** at 96:2-97:23) (3/5/03 Guglielmi *Cordis* Dep.)

At best, there exist triable issues of material fact (1) whether either inventor was aware of Target's detachment box; or (2) whether either inventor preferred the detachment box over other

---

[15] (Confidential Exhibits 20-30 to Declaration of Henry Z. Carbajal III in Support of Plaintiff's Opposition to Defendants' Motion for Summary Judgment of Invalidity of the Patents in Suit for Failure to Comply with 35 U.S.C. § 112, ¶¶ 1 and 2, **Ex. 21** at 138:11-140:23 (9/10/04 Guglielmi Dep. *Cordis*); **Ex. 22** at 350:17-353:11 (9/8/04 Guglielmi Dep.); **Ex. 23** at 466:10-467:18 (9/9/04 Guglielmi Dep.), hereafter, "Carbajal Decl.," submitted under seal.)

See also Guglielmi Decl. ¶ 9 ("In each of the two cases that occurred before our original patent filing, I used a prototype electric current generator that I made myself. At some point later, I began using a dedicated GDC generator developed by a Target engineer. That is what I used at the time our continuation-in-part application was filed. I was not involved in the design of that generator and did not have a preference for the electronics used with it."); Sepetka Decl. ¶ 12 ("I was not involved in the design of the power supply that was to be used with the GDC. In the two cases that occurred before the original patent application was filed, Dr. Guglielmi used a prototype electric current generator that he made himself. I was not involved in its design.")

electronic generators that could have been used to detach the distal tips. Accordingly, summary judgment is inappropriate.

Since the Court has found that triable issues of material fact exist with respect to each of Defendants' four best mode challenges, the Court denies Defendants' motion for summary judgment of invalidity pursuant to 35 U.S.C. § 112 ¶ 1 with respect to best mode violation.

B. Indefiniteness

Defendants move for summary judgment on the ground that particular claims of the '578, '126, '133, and '385 Patents are invalid under Section 112, paragraph 2 because the claims recite both an apparatus and a method for using the apparatus.[16] (Motion at 24-25.) The Regents contend that the challenged claims are not invalid because, in each case (1) the language at issue is contained in results-oriented "whereby" clauses that are not claim limitations or (2) the language at issue is a claim limitation that expresses a capability of the device rather than its use by a user. (Opposition at 2.)

To be patentable, an invention must be in one of four mutually exclusive statutory "classes" of subject matter: process, machine, article of manufacture or composition of matter."[17] 35 U.S.C. §101; See Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 483 (1974). The patent application must include in the specification a statement of **the claim**:

> The specification shall conclude with **one or more claims** particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

35 U.S.C. §112 ¶ 2 (emphasis added). The appropriate class of the invention is determined from the language of the claim. See Ex Parte Forsyth, 151, USPQ 55, 56 (Bd. of Appeals 1965). It must be

---

[16] Specifically, Defendants make this contention of Claims 5 and 7 of the '578 Patent, Claims 1-9 of the '126 Patent, Claims 1-24 of the '133 Patent, and Claims 1-6 and 14-25 of the '385 Patent.

[17] Courts have recognized other types of claims which are referred to as "hybrid" claims. For example, courts have held valid "product-by-process" claims. In this case, none of the patents cited in the motion are hybrid claims. Therefore, the Court does not discuss these types of claims. The Court notes, however, a hybrid claim must fall within one of the mutually exclusive statutory classes. See e.g., In re Thorpe, 777 F.2d 695 (Fed. Cir. 1985).

clear from the wording of the claim that it is drawn to only one statutory class. Id. Although a patent may contain multiple claims from multiple classes, each individual claim must be for an invention in a single class. Ex Parte Lyell, 17 U.S.P.Q. 2d 1548, 1551 (Bd. Pat. Appeals & Interf. 1990) (citing Robinson's "Treatise on the Law of Patents" (1890), at ¶ 511, p. 118).

It is well established that a claim that recites both an apparatus and a method of using that apparatus is *per se* indefinite under Section 112, paragraph 2. IPXL Holdings, L.L.C. v. Amazon.com, Inc., 430 F.3d 1377, 1383-84 (Fed. Cir. 2005). This is because, if these two separate statutory classes of invention were combined, "a manufacturer or seller of the claimed apparatus would not know from the claim whether it might also be liable for contributory infringement because a buyer or user of the apparatus later performs the claimed method of using the apparatus." Id. That is, such a claim does not provide competitors with an accurate determination of the protection provided by the patent. Id.

Thus, a claim is indefinite for impermissibly mixing classes if it includes limitations[18] claiming an invention in multiple classes. However, not every reference to an apparatus in a process claim or vice versa is prohibited as long as it is clear from the language of the claim that the reference is not being claimed as an invention. For example, courts have recognized that a patent to a new process is not rendered invalid simply because it refers to an apparatus which can be used to practice the process. Similarly, a patent on the invention of a new machine for performing a known process is not rendered invalid simply because it refers to the process:

> For if the operation performed by the machine is new in reference to the object upon which it is employed, a new process has been invented; and this is no less true if the machine or instrument employed is new than if it were old, or if the process can be performed in no other known way than by this particular machine. While on the other hand, if the operation is known in reference to the object, the invention of a new machine for performing it does not make a new process, but only a new instrument for applying it.

---

[18] The words of a patent claim describe the invention by a series of limiting words or phrases. Because patent claims are composed of a number of limitations, the limitations have on occasion been referred to as "claim elements." See Robert L. Harmon, Patents and the Federal Circuit, 362-363 (7th ed. 2005). Normally, the "preamble" and the "whereby" clauses are not limiting, and thus are not considered when deciding if the claim impermissibly mixes classes.

In Re Application of Tarczy-Hornoch, 397 F.2d 856, 867 (C.C.P.A. 1968).

In IPXL Holdings, the Federal Circuit affirmed the district court's finding that a claim was invalid for impermissible mixing of classes. The claim language at issue stated:

> The system of claim 2 [including an input means] wherein the predicted transaction information comprises both a transaction type and transaction parameters associated with that transaction type, and **the user uses the input means** to either change the predicted transaction information or accept the displayed transaction type and transaction parameters.

430 F.3d at 1384 (emphasis in original). In commenting on why this language violated the rule against impermissible mixing of classes, the Federal Circuit stated:

> Thus, it is unclear whether infringement of claim 25 occurs when one creates a system that allows the user to change the predicted transaction information or accept the displayed transaction, or whether infringement occurs when the user actually uses the input means to change transaction information or uses the input means to accept a displayed transaction. Because claim 25 recites both a system and the method for using that system, it does not apprise a person of ordinary skill in the art of its scope, and is invalid under section 112, paragraph 2.

Id.

The Court applies the legal principles above to determine whether the patent claims, as Defendants contend, impermissibly mix classes.

The first is Claim 5 of the '578 Patent, which provides:

> The apparatus of claim 1 where said connecting segment electrolytically detaches said distal tip from said wire by electrolytically disintegrating at least one portion of said connecting segment extending between said wire and said distal tip.

From its introductory clause, Claim 5 is being asserted in the apparatus class. The issue is whether the reference in Claim 5 to how the detaching takes place impermissibly claims an invention in the process class. The Court finds that it does not.

Claim 5 depends from Claim 1, which discloses as an element: "an electrolytically detachable connecting segment coupling said distal tip and said wire." Unquestionably, this and the other elements of Claim 1 place Claim 1 in the apparatus class. As a dependent claim, Claim 5 limits the way the "electrolytically detachable connecting segment" functions, namely "by electrolytically disintegrating." Using functional language, i.e., defining an apparatus by what it

does as opposed to what it is, is not in and of itself, impermissible; further, its use as a limitation does not mix an apparatus claim with a process claim. See In re Swinehart, 439 F.2d 210 (C.C.P.A. 1971).[19]

Claim 7 of the '578 Patent provides:

> The apparatus of claim 1 further comprising a catheter in which said wire, distal tip and connecting segment are disposed, and where said connecting segment is retained with said catheter and not at first exposed to said fluid to allow formation of said occlusion about said distal tip, and is then subsequently extended out of said catheter and exposed to said fluid to separate said distal tip from said wire.

Claim 7 adds as a limitation to Claim 1 a new element, namely, "a catheter in which said wire, distal tip and connecting segment are disposed." The issue is whether the additional language impermissibly mixes a process invention with an apparatus invention.

The additional language contains three clauses each introduced by the conjunction "and:"

(1) **and** where said connecting segment is retained with said catheter

(2) **and** not at first exposed to said fluid to allow formation of said occlusion about said distal tip

(3) **and** is then subsequently extended out of said catheter and exposed to said fluid to separate said distal tip from said wire.

One of ordinary skill in the art reading the claim language would understand that each of the "**and phrases**" are cumulative limitations on the "connecting segment."

"And Phrase" (1) limits the connecting segment to being "retained" with the catheter. This means that the connecting segment is kept within the catheter.

"And Phrase" (2) limits the connecting segment to being "not at first" exposed to ionic fluid to "allow" formation of an occlusion around and about the distal tip.[20]

---

[19] The Court's acceptance of functional claiming is without prejudice to an argument that the claim is anticipated or obvious with respect to prior art, which contains the same function.

[20] The Court notes that there is no disclosure of how an occlusion is "allowed" to form about the tip. The tip is disposed in the catheter. There is no disclosure of it being extended out of the catheter. However, this is an apparatus claim. The disclosure of movement of the distal tip outside of the catheter is not necessary to patentability.

"And Phrase (3) discloses an action which is taken "subsequently" to retention, namely, the connecting segment is extended out of the catheter in order to expose it to the ionic fluid and to separate the tip from the wire. This latter phrase arguably mixes the invention of a process step with the invention of an apparatus within the meaning of IPXL Holdings.

Admittedly, the language of Claim 7 does not contain the explicit language found impermissible in IPXL Holdings, "and **the user uses the input means** to either change the predicted transaction information or accept the displayed transaction type and transaction parameters." However, omission of the word "user" does not rescue a claim from risk of invalidity if it is ambiguous whether it claims an invention of both an apparatus and of a method of using the apparatus. A fair reading of Claim 7 is that it claims invention of an apparatus, i.e., "an electrolytically detachable connecting segment" and a process for using the apparatus, i.e., "[the connecting segment] is then subsequently extended out of the catheter [by the user][21] and exposed to said fluid to separate said distal tip from said wire." Accordingly, the Court finds that it would benefit from further briefing by both parties with respect to whether Claim 7 is indefinite under rules against mixing more than one class in a single claim.

Further, the Court has reviewed the language of the remaining claims cited by Defendants as indefinite on the basis of impermissible mixing of classes in a single claim.[22] Defendants have neither provided the Court with precise references to the language of the claims nor with argument why that language introduces impermissible limitations. Many of the cited claims contain non-limiting "whereby" clauses. To the extent Defendants based their motion with respect to a particular

---

[21] The bracketed language is inserted to indicate that inherent in the language of Claim 7 is a limitation that the connecting segment is extended by a user. There is no mechanism for self-extension. The inventor chose to use the action phrase "is extended" in this claim, rather than the descriptive phrase "is extendable." On the other hand, the Court notes that the subject "and phrase" is written in the passive voice, which stresses that something is happening to some object, or that the object is in a certain state. There is no explicit claim of an action. If adopted, this latter interpretation would mean that the subject phrase explains how the device functions, without claiming a method step.

[22] Claims 1-9 of the '126 Patent, Claims 1-24 of the '133 Patent, Claims 1-6 and 14-25 of the '385 Patent.

claim on the language of a non-limiting "whereby" clause, the motion is DENIED and may not be renewed. To the extent Defendants based their motion on a limitation of a particular claim, the motion is DENIED without prejudice to being renewed with specific reference to the impermissible limitation.

V. CONCLUSION

The Court DENIES Defendants' Motion for Summary Judgment on the issues of best mode violations and indefiniteness. Motions made pursuant to this Order shall be noticed in accordance with the Civil Local Rules of the Court.

Dated: July 9, 2007

/s/
JAMES WARE
United States District Judge

THIS IS TO CERTIFY THAT COPIES OF THIS ORDER HAVE BEEN DELIVERED TO:

Allison H Stiles astiles@goodwinprocter.com
Amanda Marie Kessel akessel@goodwinprocter.com
Autumn Noelle Nero autumn.nero@hellerehrman.com
Charlene M. Morrow cmorrow@fenwick.com
Charles G. Curtis ccurtis@hewm.com
Chien-Ju Alice Chuang achuang@fenwick.com
Christopher T. Holding cholding@goodwinprocter.com
Colin G. Sandercock csandercock@proskauer.com
David Edwin Jones dejones@hewm.com
David J. Harth dharth@hewm.com
David L. Anstaett david.anstaett@hellerehrman.com
Gabrielle E. Bina gbina@hewm.com
Henry Zuzueta Carbajal hcarbajal@fenwick.com
J. Anthony Downs jdowns@goodwinprocter.com
John S. Skilton jskilton@hewm.com
John S. Skilton jskilton@hewm.com
Julie Lynn Fieber jfieber@flk.com
Lissa Rose Koop Lissa.Koop@Hellerehrman.com
Lynn H. Pasahow lpasahow@fenwick.com
Michael Francis Kelleher mkelleher@flk.com
Michael G. Strapp mstrapp@goodwinprocter.com
Michael J. Shuster mshuster@fenwick.com
Michael K. Plimack mplimack@hewm.com
Michelle M. Umberger mumberger@hewm.com
Nicole Elise Perroton nperroton@goodwinprocter.com
Patrick E. Premo ppremo@fenwick.com
Patrick S. Thompson pthompson@goodwinprocter.com
Paul F. Ware pware@goodwinprocter.com
Rita A. Hao rita.hao@ucop.edu
Roland Schwillinski rschwillinski@goodwinprocter.com
Sarah C. Walkenhorst swalkenhorst@hewm.com
Wendy Lynn Bjerknes Wbjerknes@fenwick.com

Dated: July 9, 2007

Richard W. Wieking, Clerk

By: /s/ JW Chambers
Elizabeth Garcia
Courtroom Deputy

United States District Court
For the Northern District of California